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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/686,911

10/16/2003

Anthony E. Winston

51000

7470

7590

05/22/2006

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EXAMINER

KRASS, FREDERICK F

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/686,911	Applicant(s) WINSTON ET AL.	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Previous Rejections

Unless specifically maintained infra, all previous rejections are withdrawn.

Obviousness Rejection (New)

Claims 1, 3, 4, 6, 8-24 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (USP 6,248,310 or 6,214,321).

The rejection has been changed from one of anticipation under 35 U.S.C. 102 to one of obviousness under 35 U.S.C. 103 because of Applicant's amendment reciting i) at least 40 percent by weight bicarbonate (claims 1, 3, 4 and 6-20) and ii) a molar ratio of carbonate salt to calcium salt of about 0.2:1 to 1:1 (claims 21-24 and 26-30).

Applicants note that, in contrast to the prior art, they claim at least 40 wt% bicarbonate salt in combination with a carbonate salt. It is noted that the carbonate salt is present in an amount sufficient to prevent the bicarbonate from reacting with the calcium to form carbon dioxide, as outlined at page 12, lines 5-10 of the application. (Remarks, page 8, paragraph 3).

This observation is acknowledged. Although the prior art no longer anticipates the instantly claimed subject matter it still renders same obvious, however; the percentage ranges taught for each component all continue to fall (individually) within the scope of the instant claims.

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Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). Similarly, the determination of optimal values within a disclosed range is generally considered obvious. In re Boesch, 205 USPQ 215 (CCPA 1980). See also In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003). (That court reaffirming the previous Aller and Boesch decisions, stating at page 1330 that: “[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a set of disclosed percentage ranges is the optimum combination of percentages.”) It would have been obvious to have varied the relative proportions of the various components of the prior art within their disclosed ranges to determine workable and/or optimal percentages for each, consonant with the reasoning of such precedent.

Applicant further notes:

The carbonate and bicarbonate salts disclosed in the Lee et al. patents are for the purposes of merely providing an alkaline material. No other purpose or advantage of these bicarbonate and carbonate salts is believed to be set forth. See p. 5, lines 14-17 of the application. The patents to Lee ‘require [] an alkaline material so that the second composition has a pH greater than 7, preferably 7.2 to 11, more preferably from 8 to 10, optimally from 8.5 to 9.5. Alkaline materials suitable to achieve the pH are sodium bicarbonate, potassium bicarbonate, sodium carbonate, potassium carbonate, calcium carbonate, calcium oxide, sodium hydroxide, potassium hydroxide and mixtures thereof See ‘310 col. 3, Ins. 55-62 and ‘321 col. 3, Ins. 39-45. Thus, in Lee, sodium bicarbonate and sodium carbonate are equivalent.

The present invention however does not use the carbonate and bicarbonate salts for a single purpose of buffering a solution as in Lee. The present application identifies different functions for the bicarbonate

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and carbonate salts. The carbonate serves 'to help stabilize the composition by inhibiting reaction between the calcium salt and fluoride salt', see p. 11 of the application, emphasis added. The bicarbonate is well known in the art of oral care 'for providing good plaque removing capabilities... [and] a clean fresh feeling in the oral cavity after brushing and rinsing with water.' See application, Ins. 14-17. Though Lee discloses bicarbonate and carbonate salts, Lee fails to anticipate the present invention which uses a combination of bicarbonate salt at a specified level for providing good plaque removing capabilities and oral health and carbonate salts for inhibiting the reaction of calcium salt and fluoride salts. Lee does not anticipate such a combination. (Remarks, passage bridging the bottom of page 8 to the top of page 9).

These arguments are not persuasive. There does not exist, insofar as the examiner is aware, any rule of practice or legal precedent requiring the motivation for modifying a prior art teaching be the same as Applicant's. In the instant case, the motivation arises from established precedent concerning the determination of workable/optimal percentages, as discussed supra. Moreover, since it is generally known that alkali metal compounds such as sodium carbonate improve the storage stability of dentifrices containing reactive components by preventing the formation of gaseous byproducts, this result is not seen to be "unexpected" as asserted by Applicant.¹

Applicant additionally argues that the mere presence of the claimed ingredients in the prior art only supports the idea that virtually all inventions are combinations of old elements. Thus, despite the list of the presently claimed elements in the patents to Lee,

¹ See, e.g., Santalucia et al (USP 5,565,190) at column 1, lines 26-39; column 2, lines 20-26; and column 4, lines 6-14. This patent is cited only to provide factual support for the examiner's response to Applicant's assertion of unexpected results, and is not being used a substantive basis for the rejection *per se*.

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Lee fails to show the specific combination as presently claimed that being at least 40 wt% sodium bicarbonate and a carbonate. (Remarks, p. 9, second paragraph).

Again, this is not found persuasive. The argument deals with anticipation, but the rejection is now one of obviousness. Merely varying the relative percentages of old elements to arrive at workable/optimal values is in fact generally obvious, as discussed supra.

Regarding the newly added claims, Applicant states:

New claims 21-30 are directed to a two part oral composition, the first part being at least one partially water soluble calcium salt, the second part having a fluoride salt, a bicarbonate salt, and a water soluble carbonate salt being present in a specific ratio to the calcium salt present in the composition... With regard to the ratio, Examiner has asserted that working example 3 at col. 7 of the '310 patent has the relative proportion of sodium carbonate to calcium salt falling within the ratio recited in original claim 13. However, the working example 3 at col. 7 of the '310 patent does not teach the ratio of carbonate salt to calcium salt as recited in new claim 21. Applicants recognize the '310 and '321 patents disclose a combination of alkali metal bicarbonate salt and alkali metal carbonate salt which is used at levels of 0.4% by weight, see example 3 in each 6,248,310 and 6,214,321. The relative proportion of sodium carbonate to calcium salt, e.g. monocalcium phosphate, in '310 shows a 0.15 ratio, which is less than the newly claimed molar ratio of from about 0.2:1 to about 1:1 for a carbonate salt to calcium salt. The presently claimed ratio of carbonate salt to calcium salt is important 'to aid in preventing the calcium/bicarbonate salt reaction....' See p. 12 Ins. 5-10 of the application. (Remarks, page 10, first paragraph).

This argument too is not persuasive. The term "about" permits some tolerance. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946), where "at least about 10%" was held to be anticipated by a teaching of a content "not to exceed about 8%." Accordingly, in the instantly claimed value of "about" 0.2 is seen to encompass the prior art value of 0.15.

Obviousness Rejection (Previous)

1) Claims 1-6 and 8-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (USP 6,248,310 or 6,214,321), each primary reference being considered individually and separately, and each being taken further in view of Gaffar et al (USP 4,177,258).

This rejection is maintained, and is now applicable to newly added claims 21-24 and 26-30 as well.

Applicant has argued this rejection based on the differences discussed supra. Accordingly, the comments made by the examiner in conjunction therewith apply with equal force here.

2) Claim 7 was rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (USP 6,248,310 or 6,214,321), each primary reference being taken individually and separately and each being taken further in view of Winston et al (USP 6,159,449).

This rejection is maintained, and is now applicable to newly added claim 25 as well.

Applicant has argued this rejection based on the differences discussed supra. Accordingly, the comments made by the examiner in conjunction therewith apply with equal force here.

Action is Final, Necessitated by Amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

